DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2015. Misbranding of Procon Tablets and Orimbo Tablets; adulteration and misbranding of Hi-Test Vegetable Compound. U. S. v. The Allied Pharmacal Company and Samuel A. Salzman. Pleas of guilty. Fine, $1,000 and costs against each defendant; fine against partnership suspended. (F. D. C. No. 20105. Sample Nos. 20253–H, 20255–H, 22454–H.)

INFORMATION FILED: August 1, 1946, Northern District of Ohio, against the Allied Pharmacal Company, a partnership, Cleveland, Ohio, and Samuel A. Salzman, a partner.

ALLEGED SHIPMENT: Between the approximate dates of October 25, 1944, and March 3, 1945, from the State of Ohio into the States of Kansas and Missouri.

PRODUCT: Analysis of the *Procon Tablets* showed that the article contained methenamine, potassium bicarbonate, and plant material, including alkaloid-bearing drugs, such as belladonna and nux vomica. Analysis of the *Orimbo Tablets* showed that the article contained glandular substances, nux vomica and phosphate. Analysis of the *Hi-Test Vegetable Compound* showed that the article contained little or no vitamin B_1.

LABEL, IN PART: "Procon Tablets * * * Distributed by Erie Laboratories Cleveland, Ohio," "Orimbo Tablets * * * Distributed by The Allied Pharmacal Co. Cleveland, Ohio, U. S. A." and "Hi-Test Vegetable Compound With Thiamin Chloride B–1 * * * Distributed by Hi-Test Pharmacal Co. Cleveland, Ohio."

NATURE OF CHARGE: *Procon Tablets*, misbranding, Section 502 (a), the name "Procon" and the label statements, "For the temporary relief of incontinence" and "If incontinence persists, consult your physician," were false and misleading. The name and the label statements represented and suggested that the article would be effective for the relief of incontinence. The article would not be effective for such purpose.

Orimbo Tablets, misbranding, Section 502 (a), the labeling of the article failed to reveal the fact that orchic substance is of no therapeutic value when taken by mouth, which fact was material in the light of the representations displayed upon the bottles of the article, "Orchic," "Orchic Substance . . . 0.05 gr." and "Dosage: 2 to 3 tablets."

Hi-Test Vegetable Compound, adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it was represented to contain 250 units of vitamin B_1 to each ounce, but it contained little or no vitamin B_1. Misbranding, Section 502 (a), the following statements on the label were false and misleading: "Vegetable Compound with Thiamin Chloride B–1 * * * Active Ingredients Crystalline Vitamin B–1" and "Each ounce contains 250 units of B–1. The daily average dose of 3 tablespoonsful supply the full daily requirement of B–1." These statements represented and suggested that vitamin B_1 was an active ingredient of the article; that 250 units of vitamin B_1 were contained in each ounce of the article; and that 3 tablespoonsful of the article would supply the full daily requirement of vitamin B_1. Vitamin B_1 was not an active ingredient of the article, 250 units of vitamin B_1 was not contained in each ounce of the article, and 3 tablespoonsful of the article would not supply the full daily requirement of vitamin B_1, because the article contained little or no vitamin B_1.

DISPOSITION: October 22, 1946. Pleas of guilty having been entered on behalf of both defendants, the court imposed a fine of $1,000, plus costs, against each defendant. The fine against the partnership defendant was suspended.

2016. Adulteration and misbranding of Syrup Tolu & Lobelia Compound, and Syrup Tolesol. U. S. v. The P. J. Noyes Co. Plea of nolo contendere. Fine, $200. (F. D. C. No. 20920. Sample Nos. 12459–H, 12784–H, 12790–H.)

INFORMATION FILED: September 26, 1946, District of New Hampshire, against the P. J. Noyes Co., a corporation, Lancaster, N. H.

ALLEGED SHIPMENT: On or about September 13, 1945, and February 4, 1946, from the State of New Hampshire into the States of Maine and Massachusetts.

LABEL, IN PART: "Syrup 3 Fl. Ozs. Tolu & Lobelia Compound With Morphine 5% Alcohol. Each Fluidounce Contains: Morphine Sulfate, 1–4 Gr.," or "Syrup 4 Fl. Ozs. Tolesol 5% Alcohol Each Fluidounce Contains: Morphine Sulfate, 1–4 Gr."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the products differed from that which they purported and were represented to possess, since each drug contained considerably less than ¼ grain of morphine sulfate in each fluid ounce.

Misbranding, Section 502 (a), the label statement, "Each Fluidounce Contains: Morphine Sulfate, 1–4 Gr.," was false and misleading.

DISPOSITION: October 9, 1946. A plea of nolo contendere having been entered on behalf of the defendant, a fine of $200 was imposed.

2017. Adulteration of sweet oil and misbranding of isopropyl alcohol compound. U. S. v. Pennex Products Co., Inc., and Martin Sachnoff. Pleas of nolo contendere. Fine of $100 and costs against corporate defendant; fine of $10 against individual defendant. (F. D. C. No. 20949. Sample Nos. 10061–H, 10385–H.)

INFORMATION FILED: October 16, 1946, Western District of Pennsylvania, against the Pennex Products Co., Inc., Pittsburgh, Pa., and Martin Sachnoff, secretary of the corporation.

ALLEGED SHIPMENT: On or about April 3 and October 11, 1945, from the State of Pennsylvania into the States of West Virginia and Ohio.

LABEL, IN PART: "Hospital Isopropyl Alcohol Compound," or "Pennex Brand Sweet Oil."

NATURE OF CHARGE: *Sweet Oil*, adulteration, Section 501 (b), the article purported to be and was represented as *sweet oil*, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from, and its quality and purity fell below, the official standard since it did not consist of the fixed oil obtained from the ripe fruit of *Olea europoea* Linné, as prescribed by the Pharmacopoeia, but did consist of cottonseed oil.

Isopropyl Alcohol Compound, misbranding, Section 502 (a), the label statement "Isopropyl Alcohol 70% by volume" was false and misleading since the article contained less than 70 percent of isopropyl alcohol by volume.

DISPOSITION: November 4, 1946. Pleas of nolo contendere having been entered, the court imposed a fine of $100 and costs against the corporate defendant and a fine of $10 against the individual defendant.

2018. Adulteration of Aciform II. U. S. v. 4 Vials and 6 Boxes of Aciform II. Default decree of condemnation and destruction. (F. D. C. No. 20103. Sample Nos. 45066–H, 45067–H.)

LIBEL FILED: June 12, 1946, Southern District of California.

ALLEGED SHIPMENT: On or about March 18, 1946, by the Aciform Sales Corporation, from Chicago, Ill.

PRODUCT: 4 30-cc. vials, 4 boxes, each containing 12 1-cc. ampuls, and 2 boxes, each containing 12 2-cc. ampuls, of *Aciform II* at Los Angeles, Calif.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess, since it purported to be for intravenous use and contained undissolved material, whereas an article intended for intravenous use should be free from undissolved material.

DISPOSITION: July 12, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

2019. Adulteration of dextrose and sodium chloride injection. U. S. v. 177 Flasks of Dextrose and Sodium Chloride Injection. Default decree of condemnation and destruction. (F. D. C. No. 21162. Sample No. 59927–H.)

LIBEL FILED: October 7, 1946, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about July 25, 1946, by Readyflask, Inc., from Cleveland, Ohio.

PRODUCT: 177 1-liter flasks of *dextrose and sodium chloride injection* at McKees Rocks, Pa. The United States Pharmacopoeia specifies that Injection Dextrose and Sodium Chloride, which the product purported to be, must conform to the official pyrogen test. Examination showed that the article failed to comply with this test since it contained pyrogens.

LABEL, IN PART: "Dextrose 5% w/v in Isotonic Solution of Sodium Chloride, U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be *dextrose and sodium chloride injection*, a drug the name of which is recognized